INTRODUCTION

Conductive hearing loss is a major symptom of chronic otitis media. The perforation of the tympanic membrane itself causes only a mild hearing loss, but ossicular chain (OC) lesion significantly worsens the hearing threshold. OC involvement is more common in cholesteatoma, but its prevalence in chronic suppurative otitis media (CSOM) without cholesteatoma can also be estimated even up to 33% [1]. Since >300 million individuals are estimated to suffer from CSOM worldwide, of which the majority reports a significant hearing loss [2], the detection and surgical management of lesions of the OC are crucial to improve the quality of life for such patients.

The incus is the most frequently affected ossicle; however, the stapes and the malleus can be involved solely or in combination as well [3, 4]. The usual sequel of inflammation is necrosis, especially at the incudostapedial joint, on the lenticular process and the distal part of the long process of the incus, but destruction of the stapes superstructure or, rarely, of the malleus handle can also occur. In addition to necrosis, immobility of the ossicles due to adhesions, bony fixation, or tympanosclerosis as the end stage of the inflammatory process is also a possible intraoperative finding [5]. In contrast to the evaluation of the destruction of the ossicles, the type of OC lesion does not affect outcomes. Primary surgeries provide better results, but that is not due to a difference in the character of the OC lesion.

OBJECTIVES: We evaluated the pattern of ossicular chain (OC) lesion in chronic suppurative otitis media (CSOM) without cholesteatoma and its impact on outcomes in primary and revision surgeries.

MATERIALS AND METHODS: This was a retrospective chart review. Patients who underwent tympanoplasty due to CSOM with OC defect between 2010 and 2015 were included in the study.

RESULTS: OC lesions were found during 40 of 147 tympanoplasties performed due to CSOM. The preoperative air–bone gap (ABG) was greater in both discontinuity and fixation cases than in cases with CSOM with an intact OC (p<0.001). Twenty-nine patients were followed up postoperatively, after excluding four patients with stapes footplate fixation, in whom stapedotomy was not performed simultaneously. Among the 29 patients, the audiological results were similar in cases of discontinuity and fixation regarding gap change, residual ABG, and the rate of successful ossiculoplasty. Primary tympanoplasties provided better results according to postoperative ABG and the rate of successful ossiculoplasty than revision surgeries (p<0.05); however, similar patterns of OC lesions were found during primary and revision surgeries.

CONCLUSION: Both OC discontinuity and fixation occur in CSOM in a similar distribution in primary tympanoplasties and revision surgeries. The type of OC lesion does not affect outcomes. Primary surgeries provide better results, but that is not due to a difference in the character of the OC lesion.

KEYWORDS: Chronic suppurative otitis media, ossicular chain, incus destruction, fixation, revision surgery, air-bone gap

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the detection of fixation can be challenging because mobility is measured manually by the surgeon, requiring an outstanding skill and experience in ear surgery. Mis detection of the limited ossicular mobility during tympanoplasty is a potential cause of failure in hearing improvement [6].

Despite the various patterns of OC lesions in CSOM, also including the impaired mobility of the ossicles, reports usually focus on erosive damage. However, both the character of the OC lesion and its potential relationship with the audiological outcomes in CSOM are relevant from a clinical point of view, especially in revision cases where the recurrent disease and the previous manipulation in the tympanic cavity could alter the pattern of ossicular involvement, leading to further mobility and/or fixation problems. To support this theory, we have conducted a retrospective study among our patients with CSOM and OC lesions. We aimed to assess the frequency and pattern of ossicular involvement, the distribution of the affected ossicles, the rate of discontinuity or fixation, and its impact on the audiological outcomes in a mid-term follow-up period. We have compared the outcomes of primary tympanoplasties with revision cases regarding the type of the OC lesion.

**MATERIALS AND METHODS**

The medical records and the audiological results of patients with ossicular lesion due to CSOM who were treated at our department between 2010 and 2015 were reviewed retrospectively. Patients <10 years old, those with Down or other craniofacial syndrome, and those with perforations of traumatic origin or specific inflammation (e.g., tuberculosis or granulomatosis with polyangiitis), as well as those previously treated for cholesteatoma or otosclerosis, were excluded from the study. Informed consent was obtained from all the patients who participated in the study. The study was approved by the Bajcsy-Zsilinszky Hospital’s Institutional Review Board.

Preoperatively, all the patients underwent general ENT examination, ear microscopy, and audiological assessment. Imaging of the temporal bone was not performed. Thirty-nine (40 ears) patients were found to have OC lesions and were included in the first part of the study, where the incidence and the type of the OC lesion were estimated. Thirty-eight patients were operated on one ear, and one patient was operated on both ears (24 left ears and 16 right ears). The study included 27 female and 12 male patients. The age of the patients ranged between 13 and 66 (mean=41) years. Patients were asked to come for regular follow-up visits after 3 months, 6 months, 1 year, then annually after surgery, but since we operated on patients from all over the country, long-term follow-up is a challenge due to distance and motivational problems in some cases. Hence, surgery outcomes as the second part of the present study could be analyzed only in 33 of 40 cases. Four patients, in whom stapes footplate fixation was detected and stapedotomy was not performed simultaneously, were excluded from the study. Therefore, the outcomes were analyzed in a total of 29 patients.

Tympanoplasties were performed under local anesthesia via the retroauricular approach. Underlay-placed temporal fascia to close the perforation of the tympanic membrane was used. Glass ionomer cement (GC Fuji IX GP; GC Corporation, Tokyo, Japan) was used to reconstruct the long process of the incus when there was only a mild discontinuity that could be bridged, or the incus was replaced by a columella created by the autologous cortical bone when there was an extended incus lesion. Similarly, we used a columella after the incus, and the head of the malleus was removed in cases where the head of the malleus was fixed. Mobilization was performed when adhesions around the superstructure of the stapes or the manubrium of the malleus were found. In patients with fixed stapes footplate, stapedotomy was not performed at the first stage, only the closure of the perforation of the tympanic membrane. The operations were performed by 3 different practiced surgeons at the same department (L.B., H.T., and H.B.), applying the same approach and operative technique, under the guidance of the senior author (L.B.). There was no statistical difference between the surgeons’ results. Any major complications, including iatrogenic cholesteatoma, sensorineural hearing loss, facial nerve palsy, or permanent disturbance of taste, were not experienced.

Patients were divided into 2 groups according to their OC status. The fixation group consisted of patients in whom OC was continuous, but there was a mobility disorder due to bony fixation or adhesions. The discontinuity group consisted of patients in whom discontinuity of the OC due to necrosis with or without fixation was proven. The fixation group and the discontinuity group were compared according to the preoperative audiological results and the outcomes. Tympanoplasties as primary surgeries (PS) or reoperations (R) were also divided, with the latter being defined as having a failed previous tympanoplasty performed for the same reason. The PS and the R groups were compared according to the intraoperative findings related to the OC, preoperative audiological results, and outcomes. Two of the patients in the R group were previously operated at our institution, and all the others had been treated somewhere else. None of the patients in the R group was known to have OC lesion, except one whose necrotized long process of the incus had previously been replaced by a short columella.

The main outcome measures were graft success rate, meaning the rate of established intact tympanic membranes without lateralization or retraction pockets, and the levels of hearing improvement at the last follow-up visit. The audiological outcome measures were assessed following the recommendation of the Committee of Hearing and Equilibrium. Preoperative and postoperative hearing thresholds via air conduction and bone conduction were measured and analyzed, and air–bone gap (ABG) values were calculated. The pure tone average (PTA) threshold was determined as the mean value at 0.5-1-2-3 kHz. We have not routinely measured the threshold at 3 kHz at the time of data collection; thus, we have averaged 2 and 4 kHz thresholds in cases when it was missing. This is an acceptable and efficient way to calculate the 3 kHz threshold, especially when the interpolated value is used as an inclusion into the PTA (7). Outcomes were measured in patients with a minimum follow-up time of 3 months, and the very last follow-up control audiogram was considered as the postoperative audiogram for the purpose of the present study. “Gap change” was defined as the difference between the preoperative and the postoperative ABGs. Osciculoplasty was considered to be successful at a postoperative ABG of 20 dB or better in accordance with previous studies (8).

Categorical variables are presented as counts (percentages). Continuous variables are presented as mean. Continuous variables were
univariately compared between the groups using an exact Mann–Whitney–Wilcoxon test and a Kruskal–Wallis test; categorical variables were univariately compared using Fisher’s exact test. Pairwise comparisons were adjusted using the Holm method for multiplicity. Confounders were controlled using multivariate linear regression modeling (for continuous outcomes) or a logistic one (for binary outcomes).

The change in ABG was modeled using the change score approach. In other words, the difference between ABG preoperative and postoperative values was modeled as the response variable in a linear regression with the investigated predictors, which were the groups of primary/revision and those of fixation/discontinuity in this case as explanatory variables. The analysis of covariance approach is generally better than the change score approach or the percentage change score approach [9, 10]. In our case—a non-group membership that depends on preexisting conditions (i.e. existing before the pretest)—the situation is much less clear, and in contrast to the previous recommendations, the change score method appears to be a better choice in general [11, 12].

Calculations were performed using an R statistical program package, version 3.3.2 [13], with a custom script available from the corresponding author on request. Visualization was performed using the lattice package, version 0.20-34.

RESULTS

Of the 147 tympanoplasties performed due to CSOM in the aforementioned period, OC lesions in 40 (27.2%) cases were found. The involvement of the ossicles is presented in Figure 1. Incus lesion was the most common finding during surgeries (30 cases), of which the lenticular process or the distal part of the long process was destructed in 23 cases, and fixation was identified in 7 cases due to a bony fixation of the body or due to adhesions between the long process and the medial wall of the tympanic cavity. Involvement of the stapes was found in 17 cases, of which the superstructure was destructed in 1 case; immobility due to adhesions in the oval window niche was found in 12 cases, whereas fixed footplate was detected in 4 cases. Stapedotomy was performed during a second stage surgery for the latter 4 patients; that is why the outcomes of the primary surgery in these cases were not included in the second part of the present study. Fixation of the malleus was a less frequent lesion found in 9 cases; 5 of those patients had a malleus head fixation, and adhesions between the manubrium and the promontory were found in 4 patients. We have observed the involvement of more than one ossicle in 12 cases. Figure 2 summarizes the preoperative ABGs in all the patients with different OC conditions. The average preoperative ABG was 32.2 dB in patients with OC lesion, which was significantly wider (p<0.001) than in cases with CSOM with an intact and mobile OC (22.1 dB). This difference was also significant when patients with OC lesions were divided into 2subgroups: both patients with fixed ossicles (fixation group, n=16, preoperative ABG=28.4 dB) and patients with OC discontinuity alone or combined with fixation (discontinuity group, n=24, preoperative ABG=34.7 dB) were found to have a greater preoperative ABG (p<0.01) than those with CSOM cases with intact OC (22.1 dB), also indicating the proper diagnosis of ossicular fixation.

A follow-up period >3 months could be performed in 33 cases. Four patients with immobile stapes footplate were excluded; thus, the outcomes of 29 patients were analyzed. The average follow-up times were 19.4 (3-52) months in these cases and <12 months in 5 of the patients. Since the American Academy of Otolaryngology-Head and Neck Surgery guideline proposes 12 months of follow-up for evaluation of hearing improvement, this means a limitation of our study. Successful closure of the tympanic cavity could be achieved in 26 (89.6%) cases, reaching a gap change of 15.1 dB on average and a residual ABG of 17.2 dB. According to the 20 dB residual ABG criteria, the rate of successful ossiculoplasty was 69% (20/29). The audiological outcomes of patients with ossicular discontinuity were found to be very similar to fixation cases (Table 1); there was no statistical difference between the gap change (15.2 dB vs. 14.9 dB, p=0.9354), the residual ABG (18.3 dB vs. 14.9 dB, p=0.6511), and the rate of successful ossiculoplasty (65% vs. 77.8%, p=0.6749).
Cases were divided into 2 groups (PS and R) according to their medical history. Table 2 summarizes the outcomes in primary tympanoplasties versus revisions. With a mean follow-up time of 18.7 months in the PS group (n=14), the graft success rate was 92.9%, and a 19.4 dB gap change with a residual average ABG of 12.3 dB could be achieved. In the R group (n=15), the average follow-up period was 20.1 months; an 86.7% graft success rate could be reached, whereas the gap change was 11.1 dB with a 21.9 dB average residual ABG. The postoperative ABG was significantly lower in the PS group than in the R group (p=0.0092 when controlling for the nature of fixation/discontinuity). Successful ossiculoplasty was performed in 13 of 14 cases (92.9%) in the PS group, whereas in 7 of 15 cases (46.7%) in the R group (p=0.0174 when controlling for the nature of fixation/discontinuity). When comparing the PS group with the R group, a relatively similar character of the OC lesions was found. Discontinuity was found in 71.4% in the PS group and 66.7% in the R group. The incus was involved in 11 patients in both groups (78.6% in the PS group and 73.3% in the R group), of which fixation was detected in 1 (7.1%) case in the PS group and 2 (13.3%) cases in the R group. The stapes—but not the footplate—was affected in 5 (35.7%) patients in the PS group and in 4 (26.7%) patients in the R group, whereas the fixed malleus was found in 6 (42.9%) cases in the PS group and in 2 (13.3%) cases in the R group. There were 7 (50%) patients with multiple ossicular involvement in the PS group, but only 1 (6.7%) in the R group.

In the multivariate model, the decrease in ABG was 19.34 dB in the primary/discontinuity group. If the surgery was revision instead, this decrease is—clinically, substantially, and statistically significantly—lower by 8.34 dB (95% confidence interval (CI): -0.63-16.04 dB, p=0.0349). The nature of fixation had no impact on the change (0.2 dB higher decrease, 95% CI: -8.52-8.05 dB, p=0.9538). Figure 3 shows the mean values before and after surgery for all groups. Owing to the relatively low sample sizes and the frequency of multiple OC involvement, more detailed and separate statistical analysis of the outcomes according to the affected ossicles was not performed.

**DISCUSSION**

There is less emphasis on OC involvement in CSOM than in cholesteatoma; however, its prevalence is estimated between 8% and 33% nowadays according to contemporary literature [1, 14, 15]. We found ossicular lesion in 27.2% of our patients, which was in accordance with the literature, also indicating that OC involvement is not marginal in CSOM.

The studies focus on erosive damage to the OC, which usually means the destruction of the lenticular or the long process of the incus as the most common lesion [14], but we included cases with immobile ossicles as well. Separate analysis of ossicular destruction and fixation can be considered for pathological studies or to compare surgical techniques on the same OC lesion, but their joint discussion is reasonable from the clinical point of view. Both of them occur in CSOM because chronic inflammation can lead to mucosal changes, adhesion formation, osteogenesis, or sclerosis in the middle ear cavity, causing ossicle mobility problems in addition to destruction [5, 16]. The assessment of the mobility of the OC is more challenging than evaluating discontinuity. Destruction of the OC is usually easy to discover, and also CT scanning of the temporal bone can preoperatively help to detect discontinuity. Fixation is actually discovered during surgery, and the assessment of mobility is performed by palpation, which is purely dependent on the surgeon’s experience. Additionally, visualization of the exact site of fixation and its handling requires more surgical skills.

However, previous studies have shown that preoperative ABG can reliably predict OC defects in CSOM independent of its nature, dis-
continuity, or fixation. It was demonstrated that both the discontinuity and the fixation of the OC result in a higher ABG than in patients with CSOM but an intact and mobile OC [17]. Accordingly, a higher preoperative ABG with a continuous OC should warrant for mobility problems in CSOM. We have verified this observation in the present study because a higher preoperative ABG could be measured in our patients with OC lesions when compared with cases with CSOM without OC defects (32.2 dB vs. 22.1 dB), and that difference was also significant when patients with OC lesion were divided into groups of fixation and discontinuity (34.7 dB and 28.4 dB vs. 22.1 dB), also validating the proper diagnosis of OC fixation.

When analyzing the OC status of our patients, we also found that the incus was the most frequently affected ossicle (n=29/40) with necrosis of the lenticular or the long process (n=22/40). The pathophysiological mechanisms behind incus destruction were predominantly investigated in cholesteatoma, where damage is thought to be a multifactorial process, an imbalance of different signaling molecules and growth factors related to inflammation, and pressure could be revealed. The destructive pressure effect of the cholesteatoma is missing in CSOM; however, chronic inflammation is a similar feature that can explain ossicular erosion, but it can cause impaired mobility of the OC as well, as mentioned above. Accordingly, the fixation of the ossicles was also a regular finding among our patients, particularly the fixation of the malleus head, and a reduced movement of the manubrium, the incus, or the stapes superstructure, due to adhesions. These kinds of mobility disorders can be solved during a single-staged tympanoplasty; however, we have also found 4 cases with fixed stapes footplates. A fixed footplate leading to an unexpected staged surgery especially highlights the importance of counting with ossicular fixation in CSOM.

The primary goal of tympanoplasty in CSOM is to eradicate the disease by establishing an intact tympanic membrane that also improves hearing. The graft success rate in CSOM is reported to be between 60% and 99%, but it is usually approximately 90% [18, 19], and our results (89.6%) are in accordance with previous studies. An overall gap change of 15.6 dB could be achieved among our patients with a residual ABG of 17.2 dB, and the rate of successful ossiculoplasty (ABG ≤20 dB) was 70%, which was similar to the literature. When analyzing our results according to the type of the OC lesion, we found that the character of the OC lesion, namely, discontinuity or fixation, did not affect the hearing outcomes. There was no significant difference between the discontinuity and the fixation groups regarding the gap change, the residual ABG, and the rate of successful ossiculoplasty.

When comparing the outcomes of primary tympanoplasties with revision cases, primary surgeries appear to provide better results, both with regard to closing the perforation of the tympanic membrane and also hearing improvement, according to previous studies [4, 18, 20]. Our results were in accordance with these observations. The results were statistically better in primary surgeries than in revisions. We have hypothesized that the inferior audiological results in revision cases are in relationship with an altered pattern of the OC lesions found during revision surgeries. We have expected that the previous manipulation in the middle ear cavity, or the mucosal changes caused by the recurrent disease, or both, lead to a shift toward fixation or multiple ossicular lesions. Surprisingly, we have also found that not only the pattern of the OC lesion was very similar in the primary and the revision cases regarding to the involvement of the ossicles and the occurrence of discontinuity and fixation, but also multiple ossicular involvement was shown even more frequently during primary tympanoplasties than during revision surgeries.

This means that the pattern of the ossicular involvement is not modulated by the recurrent disease or previous surgeries, and it is not the cause of the difference in the audiological results between the primary tympanoplasty cases and the revision surgery cases. However, the chance to develop mild restrictions in the mobility of the OC, below the manually detectable range, is theoretically higher in revision cases. Objective measurements could help to clarify this question by evaluating mobility in a more precise, reliable, and reproducible manner during middle ear surgery, such as using the Laser Doppler vibrometry, of which extended in vivo use was recently published [21]. However, since these measurement tools are not routinely available yet, and the patients’ willingness for further trials after one or more unsuccessful tympanoplasties is finite, the role of latent OC mobility in the inferior results of revision surgeries remains the subject of speculation.

CONCLUSION
Both OC discontinuity and fixation can be found in CSOM in a relatively similar distributional tendency when comparing primary tympanoplasties with revision surgeries. Our results suggest that the type of OC lesion does not affect outcomes with the exception of fixed stapes footplate. Despite that, primary surgeries provide better results than revisions, but that is not due to a difference in the character of the OC lesion.

Ethics Committee Approval: The study was approved by the Bajcsy-Zsilinszky Hospital's Institutional Review Board.

Informed Consent: Informed consent was obtained from patients who participated in this study.

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Conflict of Interest: The authors have no conflict of interest to declare.

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